JC05 Rec'd PCT/PTO 19 APR 2001

FORM PTO-1390 (REV. 1-98) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371	41482/205539
	U.S. APPLICATION NO. (If known, see 37 CFR 1 5) 09/807906 UNKNOWN

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US99/26265	12 November 1999 (12.11.99)	13 November 1998 (13.11.98)

TITLE OF INVENTION
PROSTHESIS AND METHODS OF INDUCING BONY INGROWTH USING ULTRASOUND THERAPY

APPLICANT(S) FOR DO/EO/US
TALISH, Roger J. and WINDER, Alan A.

Applicants herewith submit to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 37 (b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as published (35 U.S.C. 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the published International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unexecuted)
10. ☐ A translation of the annexes of the International Preliminary Examination Report under PCT Article 36
11. ☐ An Information Disclosure Statement under 37 CFR 1.197 and 1.98
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
    a. Certification Under 37 CFR 1.10

    I hereby certify that this document is being mailed to Box PCT, Commissioner for Patents, Washington, D.C. 20231, via "Express Mail Post Office to Addressee" on this 19th day of April, 2001, Express Mail Label No. EL572470413US

    Angela M. Rossi

    b. International Preliminary Examination Report with pages 1-6 of amended claims

    c. Marked up version of amended claims

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
unknown 09/807906	PCT/US99/26265	41482/205539

17. ☒ The following fees are submitted BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):		CALCULATIONS PTO USE ONLY	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO	$1,000.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$860.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2) paid to USPTO	$710.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)	$690.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)	$100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT	=	$860.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total claims	39	19	X $18.00	$342.00	
Independent claims	04	01	X $80.00	$80.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+$270.00	$.00	
TOTAL OF ABOVE CALCULATIONS			=	$1,282.00	
Reduction of ½ for filing by small entity, if applicable.			--	$.00	
SUBTOTAL			=	$1,282.00	
Processing fee of $130.00 for furnishing the English translation later than ☐20 ☒30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$.00	
TOTAL NATIONAL FEE			=	$1,282.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40 per property				$.00	
TOTAL FEES ENCLOSED			=	$1,282.00	
				Amount to be refunded:	$
				charged:	$

a. ☒ Check in the amount of $1,282.00 is enclosed.

b. ☐ Please charge my Deposit Account No. 11-0855 in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-0855.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.

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PATENT TRADEMARK OFFICE

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1145556

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Applicants Roger J. TALISH and Alan A. WINDER

International Application No.: PCT/US99/26265

U.S. Serial No.:

International Filing Date: 12 November 1999 (12.11.99)

U.S. Filing Date: 19 April 2001 (19.04.01)

For: PROSTHESIS AND METHODS OF INDUCING BONY INGROWTH USING ULTRASOUND THERAPY

Box PCT
Commissioner for Patents
Washington, D.C. 20231

Attorney Docket No. 41482/205539
Date: 19 April 2001

PRELIMINARY AMENDMENT

Sir:

Kindly amend the above-identified patent application prior to examination:

In the claims

4. (Amended) A bone prosthesis (10) as claimed in claim 1 in which at least one means for propagating acoustic energy to the corresponding bone segment comprises at least one channel.

8. (Amended) A bone prosthesis (10) according to claim 4 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.

Kindly add the following new claims:

35. (New) A bone prosthesis (10) as claimed in claim 2 in which at least one means for propagating acoustic energy to the corresponding bone segment comprises at least one channel.

36. (New) A bone prosthesis (10) as claimed in claim 3 in which at least one means for propagating acoustic energy to the corresponding bone segment comprises at least one channel.

37. (New) A bone prosthesis (10) according to claim 5 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.

38. (New) A bone prosthesis (10) according to claim 6 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.

39. (New) A bone prosthesis (10) according to claim 7 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.

Respectfully submitted,

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Marked up version of amended claims

PCT/US99/26265

4. (Amended) A bone prosthesis (10) as claimed in [either of claims 1, 2, or 3] claim 1 in which [the] at least one means for propagating acoustic energy to the corresponding bone segment comprises at least one channel.

8. (Amended) A bone prosthesis (10) according to [any one of claims 4 to 7] claim 4 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.

--35. (New) A bone prosthesis (10) as claimed in claim 2 in which at least one means for propagating acoustic energy to the corresponding bone segment comprises at least one channel.--

--36. (New) A bone prosthesis (10) as claimed in claim 3 in which at least one means for propagating acoustic energy to the corresponding bone segment comprises at least one channel.--

--37. (New) A bone prosthesis (10) according to claim 5 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.--

--38. (New) A bone prosthesis (10) according to claim 6 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.--

--39. (New) A bone prosthesis (10) according to claim 7 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.--

PROSTHESIS AND METHODS OF INDUCING BONY INGROWTH USING ULTRASOUND THERAPY

This application claims the benefit of provisional application serial number 60/108,235 filed on November 13, 1998 entitled "PROSTHESIS AND METHODS OF INDUCING BONY INGROWTH USING ULTRASOUND THERAPY".

Technical Field

The present disclosure relates to prosthetic implant devices and methods of utilizing ultrasound to induce bony ingrowth into a prosthetic device. More particularly, the present disclosure relates to prostheses which are adapted for insertion into the medullary canal of so-called "long bones" (femur, humerus, clavicle, radius, ulna, tibia, fibula, metacarpal, metatarsal and phalanges) and methods of inducing the soft cancellous bone surrounding the medullary canal to grow inwardly, i.e., "bony ingrowth", towards the prosthetic implant to stabilize the prosthesis within the medullary canal.

Background

Joint replacement, or arthroplasty, is a surgical procedure in which the diseased portions of the joint are removed and replaced with new artificial parts called a prosthesis. During typical joint replacement surgery, the surgeon removes the diseased portion of the bone, surrounding tissue and cartilage from the joint leaving the healthy parts of the joint intact. The surgeon then replaces the diseased portion of the joint with new parts which mimic the movement of the joint. For example, with hip arthroplasty, the surgeon replaces the head of the femur and the acetabulum with artificial parts made of materials which permit a natural, gliding motion of the hip joint. This generic type of device includes prostheses that have femoral components made of alloys, such as cobalt-chromium-molybdenum and/or titanium-based alloys.

In some cases the surgeon uses a special glue or cement to bond the new parts of the joint to the existing healthy bone. In other cases the artificial parts are made from a porous material which permits the patient's own bone to grow into the pores of the porous material to hold the new parts in place. See, e.g., U.S. Patent Nos. 4,536,894 to Galante et al., 5,018,285 to Zolman et al. and 5,004,476 to Cook.

Successful replacement of deteriorated, arthritic, and severely injured joints has contributed to enhanced mobility and comfortable, independent living for many people who would otherwise be substantially disabled. New

technologies involving prosthetic devices for replacement of joints, along with advances in surgical techniques, has diminished the risks associated with these operations and improved the immediate and long-term outcome of joint replacement surgery.

Questions remain, however, concerning which prosthetic designs and materials are most effective for specific groups of patients and which surgical techniques and rehabilitation approaches yield the best long-term results. For example, patients whose joints have been severely damaged due to osteoporosis tend to suffer from long-term difficulties with the prosthesis due to insufficient bone mass surrounding the medullary canal. Osteoporosis causes abnormally porous and fragile bones due to age, low calcium intake, inadequate physical activity, certain drugs, estrogen deficiency, hormone disorders, nutritional disorders, bone disuse and family history of the disease. Implanting a prosthetic device into such porous and fragile bones has had limited success and may require a repeat/revision procedure or long therapy. Issues also exist regarding the best indications and approaches for revision surgery.

Nevertheless, further improvements in the total design of joint prostheses are needed to facilitate more stable fixation of the implanted prosthesis at the bone/metal interface. For example, with cemented prosthetic devices fixation problems can occur due to the various stress loads, i.e., the compression, shear and torsion to which the implanted device is subjected.

These mechanical forces, especially shear and torsion, as well as other factors such as osteoporosis, weaken the bone-cement bond. In addition, it is known that there is a tendency for bone resorption which also weakens the cement bond between the intramedullary canal of the bone and the prosthesis.

By providing a bony ingrowth surface on the prosthetic device and/or by providing therapy for inducing bony ingrowth into the prosthetic device, a more stable fixation can be made. However, with conventional prosthetic device treatments/ techniques which include bony ingrowth surfaces, sufficient bony ingrowth for long term stabilization typically requires the prosthesis to be stably fixed for at least six weeks after surgery, and any relative motion of the prosthesis during that period prevents or minimizes bony ingrowth. This is a particularly significant problem in view of the difficulty in fitting the prosthesis with sufficiently close tolerances to provide large contact areas between the porous material and the bone, even where the entire outer surface of the prosthesis is fabricated from porous material. For example, it has been reported that an instance of 10 to 20 percent of femoral stem loosening or failure in total hip arthroplasty patients followed over five or more years, especially in younger patients.

The present disclosure also relates to directing ultrasonic energy in relatively low levels into living tissue to stimulate ingrowth of the soft bone surrounding the medullary canal into the prosthesis. The disclosure also includes

various techniques for the transdermal delivery of acoustic energy through body tissue and/or fluids to propagate resonant waves along the inner cavity and/or outer surface of the prosthesis to stimulate ingrowth of the surrounding soft cancellous bone about the periphery of the medullary canal.

Acoustic bone fracture repair techniques and parameter preferences are discussed in detail in U.S. Patent No. 5,520,612 which is incorporated herein by reference. Much like bone fracture repair, acoustic techniques to stimulate bony ingrowth are also subject to a range of values best determined by professional experience. However, it is nevertheless helpful to list certain parameter considerations which may play a significant role in promoting ingrowth:

1) The frequency of surgically non-invasive acoustic delivery into the body should be carefully calculated and monitored to insure steady standing-wave development within the medullary canal;

2) The frequency of the transducer (or other carrier) should be adjustably selectable, with provision for frequency sweeping between adjusted limits; and

3) The frequency of pulse modulation should be adjustably selectable, with provision for frequency sweeping between adjusted limits.

SUMMARY

A bone prosthesis includes a first portion for engaging a first bone segment and at least one channel disposed within the first portion for propagating acoustic energy through the channel to the first bone segment. Preferably, the prosthesis further includes a second portion for engaging a second bone segment. The channel includes an interior reflective surface which defines a resonating chamber disposed through the first portion. In one embodiment, the resonating chamber includes at least one opening for receiving acoustic energy. In another embodiment, the resonating chamber is convoluted.

Another embodiment of the bone prosthesis includes a first portion for engaging a first bone segment and a second portion for engaging a second bone segment. At least one of the portions includes at least one means for propagating acoustic energy to the corresponding bone segment. Preferably, the propagating means includes: a transducer collar which engages one of the portions; a transducer disposed adjacent one of the portions; and/or a piezoelectric/piezoceramic membrane material which is disposed between a porous material wrapped around the prosthesis and the outer periphery of the prosthesis.

In another embodiment, the bone prosthesis includes a ball portion for engaging the acetabulum of the pelvic bone and the first portion is an implant for engaging the medullary canal of the femur. In yet another embodiment, the first portion engages the medullary canal of the humerus and a second portion engages the medullary canal of the ulna and the first and second portions move relative to one another about a pivot.

In still another embodiment, the first portion engages the femur and the second portion engages the tibia. The first and second portions are movable relative to one another upon movement of one of the femur and the tibia. Preferably, the first portion includes at least one dowel which engages a corresponding bore associated with the femur and the second portion includes at least one dowel which engages a corresponding bore associated with the tibia. The channel includes an interior reflective surface which defines a resonating chamber disposed through each of the dowels.

The present disclosure also relates to a method for measuring the stability of an implanted prosthesis and includes the steps of: a) providing a source having a probe for sending and receiving signals and a comparator for comparing and analyzing prior signal data with newer signal data; b) placing the probe adjacent the prosthesis; c) transmitting an initial signal through the probe to the prosthesis; d) receiving a return signal from the probe after the signal

propagates and returns through the prosthesis; e) storing the return signal data; f) repeating steps (a) through (e); and g) comparing and analyzing stored return signal data to determine implant stabilization.

Another embodiment of the present disclosure relates to a method for measuring the stability of an implanted prosthesis and includes the steps of: a) providing a source having a probe for sending signals and a comparator for comparing and analyzing prior signal data with newer signal data; b) providing a receiving sensor which connects to the source and monitors the signals as the signals propagate through the prosthesis; c) placing the probe adjacent the prosthesis; d) placing the receiving sensor along the prosthesis; e) transmitting signals through the probe to the prosthesis; f) monitoring the signal with the receiving sensor as the signal propagates through the prosthesis; g) storing the signal data; h) repeating steps (a) through (g); and i) comparing and analyzing stored signal data to determine implant stabilization.

Another embodiment relates to a method for stabilizing an implanted prosthesis and includes the steps of: a) providing a bone prosthesis having a first portion and at least one channel for propagating acoustic energy therethrough; b) engaging the first portion within a first bone segment; and c) directing acoustic energy at the first portion such that acoustic energy is transmitted through the channel to the first bone segment to stimulate bony ingrowth.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a front view of one embodiment of the present disclosure showing a hip prosthesis implanted within the upper femur with an external transducer emitting acoustic waves at the prosthesis to stimulate bony ingrowth;

Fig. 1B is partial cross-section of the hip prosthesis of Fig. 1 showing an internal reflective surface and a resonating chamber;

FIG. 1C is partial cross-section of the hip prosthesis of Fig. 1 showing the external transducer emitting acoustic waves at the reflective surface which, in turn, directs the waves downward through the resonating chamber;

Fig. 2A is partial cross-section of an alternate embodiment of the hip prosthesis of Fig. 1 showing an internally disposed transducer mounted within the resonating chamber;

Fig. 2B is partial cross-section of the hip prosthesis of Fig. 2A showing the external transducer emitting acoustic waves at the internal transducer which, in turn, emits acoustic waves downward through the resonating chamber;

Fig. 3 is partial cross-section of an alternate embodiment of the hip prosthesis of Fig. 1 showing a resonating chamber which is configured and dimensioned in a convoluted form to maximize the interference between the acoustic wave and the internal walls of the resonating chamber;

Fig. 4 is partial cross-section of an alternate embodiment of the hip prosthesis of Fig. 1 showing a series of laterally extending slots which extend from the interior walls of the resonating chamber to the outermost periphery of the prosthesis to conduct energy directly to the inner walls of the medullary canal;

Fig. 5A is partial cross-section of an alternate embodiment of the hip prosthesis of Fig. 1 showing a transducer collar which surrounds the prosthesis and emits acoustic waves downwardly along the outer periphery of the prosthesis to stimulate bony ingrowth from the surrounding bone of the medullary canal;

Fig. 5B is partial cross-section of an alternate embodiment of Fig. 5A showing a hip prosthesis having both an internally disposed resonating chamber for internally propagating acoustic waves and a transducer collar for emitting acoustic waves downwardly along the outer periphery of the prosthesis;

Fig. 6A is a front view of an alternate embodiment of the hip prosthesis of Fig. 1 showing a piezoelectric/piezoceramic membrane material

disposed between a porous coating and the outer shell of the hip prosthesis for conducting acoustic energy to the medullary canal;

Fig. 6B is a cross section of the Fig. 6A embodiment taken along line 6B-6B;

Figs. 7A-7E are front views of various embodiments of the hip prosthesis of Fig. 1 showing various patterns disposed about the outer periphery of the prosthesis for promoting acoustic wave propagation to the medullary canal;

Fig. 8 is a front view of a diagnostic apparatus having a main transmitting unit and a send/receive probe for monitoring and recording the acoustic signals propagated through the hip prosthesis and medullary canal;

Fig. 9 is a front view of an alternate embodiment of the diagnostic apparatus having a main transmitting unit, a probe for sending acoustic waves through the hip prosthesis and a receiving sensor array probe for monitoring the acoustic signals propagated through the hip prosthesis and relaying the information back to the main unit;

Figs. 10A-10J show various views of an alternate embodiment of the present disclosure showing a knee joint prosthesis implanted between the lower

femur and the upper portion of the tibia with an external transducer emitting acoustic waves at the prosthesis to stimulate bony ingrowth;

Figs. 11A and 11B show an alternate embodiment of a knee joint prosthesis having a plurality of dowels each having an inwardly disposed resonating chamber for propagating acoustic energy therethrough to stimulate bony ingrowth;

Figs. 12A-12C show various views of an alternate embodiment of the present disclosure showing an elbow joint prosthesis implanted between the humerus and the ulna with an external transducer emitting acoustic waves at the prosthesis to stimulate bony ingrowth; and

Figs. 13A-13C show an alternate embodiment of an elbow joint prosthesis having a plurality of inwardly disposed resonating chambers for propagating acoustic energy therethrough to stimulate bony ingrowth.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1A-1C which show one embodiment of the present disclosure, namely, a hip prosthesis which is generally designated by reference numeral 10. Hip prosthesis 10 includes a head or ball portion 18 which is connected to a lower wedge-like implant member 32 by way of a neck portion

24. Preferably, the lower wedge member 32 is generally tapered such that the lowermost portion 36 is configured to facilitate insertion of the wedge member 32 into the medullary canal 38 of the femur bone 14.

As best seen in Fig. 1A, the upper end "ball" portion 18 of the prosthesis is preferably configured and dimensioned to engage the acetabulum (socket) 16 of the pelvic bone 26 in a cup-like manner. This "ball and socket" arrangement allows a wide range of motion, including sitting, standing, walking and other daily activities. Once the "ball and socket" are engaged, the muscles and ligaments 28, 32 of the upper leg, e.g., vastus lateralis and gluteus muscles, among other things, cooperate to retain the hip joint in place in much the same fashion as the ball and socket-like arrangement of the original hip.

Figs. 1A and 1C show the preferred position of the wedge member 32 implanted within the femur 14. More particularly, during hip replacement surgery, the surgeon removes the diseased portion of the bone, surrounding tissue and cartilage from the hip joint leaving the healthy parts of the hip joint intact. The upper portion of the femur bone 14 is preferably surgically reconfigured to expose the medullary canal 38 which is a generally centrally located passageway disposed within the femur 14 which extends the entire length of the same. In some cases it may be necessary to excavate the upper most portion of the canal 38 to facilitate insertion of the wedge member 32 and accommodate the wider upper portion 20 of the wedge member 32.

The surgeon then replaces the head of the femur 14, i.e., ball, and the acetabulum, i.e., socket, with new, biocompatible artificial parts, e.g., ball 18 and socket 16, made of materials which permit a natural, gliding motion of the hip joint, e.g., cobalt-chromium-molybdenum and/or titanium-based alloys. In some cases the surgeon uses a special glue or cement to bond the new parts of the hip joint to the existing healthy bone 14. In other cases the artificial parts are made from or include a porous biocompatible material which permits the patient's own bone to grow into the pores and hold the new parts in place.

It has been seen, however, that with prostheses that have been cemented in place the various stress loads, i.e., the compression, shear and torsion, to which the implanted device is normally subjected may cause the bone-cement bond to weaken. Other factors such as osteoporosis, also tend to weaken the bone cement bond.

The various embodiments of the present disclosure provide configurations which cooperate with ultrasonic therapies to induce bony ingrowth into the prosthetic device and provide a more stable fixation between the prosthesis and the bone.

As illustrated in Figs. 1A-1C, once the prosthesis has been properly implanted, the upper portion 20 of the wedge member 32 protrudes from the

upper portion of the femur 14 to expose an opening 22 disposed proximate the uppermost portion 20 of the wedge member 32. This opening 22 leads to a resonating chamber 34 which extends inwardly down the wedge member 32 towards the tapered end portion 36 as best seen in Fig. 1C.

An external ultrasonic transducer 12 is applied to the outer skin of the patient (preferably pre-treated with a lotion or gel specifically developed to reduce the chances of the skin developing rashes or burning) and emits acoustic waves 30 at frequencies of between about 5KHz to about 10kHz which are transcutaneously delivered through the body tissue and muscle 28, 32 towards the upper portion 20 of the prosthesis 10. Preferably, the acoustic wave 30 is focused at opening 22 such that the majority of the wave 30 enters through the opening 22 and into the resonating chamber 34 which is filled with a fluid to facilitate propagation of the acoustic wave 30' through the resonating chamber.

As best seen in Figs. 1B and 1C, the uppermost portion of the resonating chamber 34 is equipped with a reflective surface 42 which is specifically configured and dimensioned to reflect waves 30 downwardly through the resonating chamber 34. Preferably, the reflected waves 30' resound off the interior walls of the resonating chamber 34 and cause the prosthesis 10 to resonate.

By resonating the prosthesis 10, or a portion thereof, within the medullary canal 38 of the femur 14 at specific frequencies for short, e.g., 20 minute, periods of time on a weekly, bi-weekly, daily, or other time-specific basis, the energy will stimulate the soft cancellous bone 40 which surrounds the medullary canal 38 to grow inwardly, i.e., "bony ingrowth", and stabilize the prosthesis 10 within the femur 14.

It is contemplated that the cross-sectional areas of the resonating chamber 34 can be varied along the length thereof to adjust the depth of penetration of the propagated wave. In addition, the excitation values can be varied to promote bony ingrowth from the distal end 36 to the upper portion 20.

Preferably, the reflective surface 42 can be configured at any desired angle to resound acoustic waves 30' downward through the resonating chamber 34 to cause the prosthesis to resonate/vibrate at different frequencies. Although it is preferable to utilize a resonating chamber 34 which has a natural resonance which responds to the acoustic waves 30' being propagated therethrough, in some cases it may be desirable to configure the resonating chamber 34 to have a more cylindrical-like cross-section or some other geometrically advantageous cross-section to produce a different or specific desired resonating effect.

In some cases it may also be preferable to calibrate the transducer 12 to emit one steady frequency to resonate the prosthesis 10, or in other cases it may be preferable to sweep the modulating frequency across a wide range of frequencies to stimulate bony ingrowth. See, e.g., U.S. Patent No. 5,520,612, incorporated herein by reference.

Figs. 2A and 2B show an alternate embodiment of the present disclosure which include a hip prosthesis 110 generally configured, dimensioned and operable in the same fashion as the Figs. 1A-1C embodiment with the exception that this embodiment includes a second acoustically coupled transducer 144 disposed internally within the upper portion 120 of the wedge member 132 of the prosthesis 110. In use, the external transducer 12 emits acoustic energy (focused or unfocused) at the second transducer 144 which, in turn, emits acoustic waves 30' downward through the resonating chamber 134. Preferably, the dimensions of the second transducer 144 are matched to the frequency to facilitate wave 30' propagation through the fluid-filled resonating chamber 134 and/or the Eigen modes are matched to the cavity.

Figs. 3 and 4 show alternate configurations of the resonating chamber 334, 434 disposed within the wedge member 332, 432 of the hip prosthesis 310, 410. More particularly, Fig. 3 shows a zig-zag-like resonating chamber 334 internally disposed within the wedge member 332. It is believed that configuring the chamber 334 in this fashion will enhance vibration of the

prosthesis which will, in turn, further stimulate bony ingrowth of the soft cancellous bone 40 surrounding the medullary canal 38.

Fig. 4 shows another alternate configuration of the resonating chamber 434 wherein a series of generally laterally disposed slots 450 extend from the interior walls of the resonating chamber 434 to the outermost periphery of the wedge member 432 to propagate the acoustic energy 30' directly through the prosthesis 410 to the surrounding soft cancellous bone 40 of the medullary canal 38. It is further contemplated that structures such as biocompatible ball bearings, blades, wires, etc. can be positioned within the slots 450 to enhance the propagation of energy to the surrounding bone 40.

Fig. 5A and 5B show two additional alternate embodiments of the present disclosure incorporating a transducer collar 546 which transfers/emits acoustic waves 30' downward along the outer periphery of the wedge member 532 to stimulate bony ingrowth. More particularly and with reference to Fig. 5A, the hip prosthesis 510 of this embodiment includes a generally circular transducer collar 546 which surrounds the uppermost portion 520 of the wedge member 532. Collar 546 is activated and/or energized by the acoustic waves 30 emitted from external transducer 12 and, in turn, propagates waves 30' downwardly along the outer periphery of the wedge member 532 to stimulate ingrowth of the soft cancellous bone 40 surrounding the medullary canal.

Preferably, collar 546 can work in combination with other wave propagation devices. For example, collar 546 can work in combination with a porous material 560 which wraps the wedge member 532 and helps to propagate the acoustic wave 30' downwardly to stimulate the soft bone 40. More particularly, the acoustic wave 30' is trapped within the porous layer 560 as it travels/conducts downward through the wedge member 532 and/or the porous layer 560 acts as its own waveguide. The medullary canal of this embodiment may act as a type of waveguide further enhancing/stimulating bony ingrowth.

It is also contemplated to impinge the acoustic wave 30 from the external transducer 12 directly upon the porous material 560 above the femur 14 such that the acoustic wave 30 travels within the porous layer 560 downward along the outer periphery of the wedge member 532 without the use of collar 546.

Fig. 5B shows an alternate embodiment of the Fig. 5A embodiment wherein the wedge member 532 also includes an internally disposed resonating chamber 534 which is configured and dimensioned similar to the resonating chamber of Fig. 3 to propagate waves 30' internally through the wedge member 532. As shown in this figure, acoustic waves 30" and 30' are propagated along the outer periphery of the wedge member 532 and within the resonating chamber 534, respectively, which, it is contemplated, will have a duel effect of enhancing bony ingrowth.

Although Fig. 5B shows the resonating chamber similar to Fig. 3, it is contemplated that other embodiments of the resonating chamber described herein may be used in combination with the transducing collar 546 to enhance bony ingrowth.

Figs. 6A and 6B show yet another alternate embodiment of the hip prosthesis 610 which includes a piezoelectric/piezoceramic membrane material 670 disposed between the wedge member 632 and the porous coating 660. Preferably, the piezoelectric/piezoceramic material is activated externally, e.g., by external transducer 12, and operates to propagate acoustic energy downward along the outer periphery of the wedge member 632 to stimulate bony ingrowth from the soft bone 40 into the porous coating to stabilize the prosthesis 610.

Figs. 7A-7E show alternate embodiments of hip prosthesis wherein the outer periphery of the wedge member 732 is patterned to conduct/transmit acoustic waves 30 directly into the medullary canal 38. For example, the different patterns of the wedge member 732 can include grooves or channels (Figs. 7A and 7B), honeycomb patterns (Fig. 7C), semi-circular/spiral groove patterns (Fig. 7D) and/or a series of longitudinally or laterally oriented zig-zag patterns (Fig. 7E). These patterns have a two-fold effect: 1) to directly conduct acoustic waves 30 into the medullary canal 38 to stimulate bony ingrowth; and 2) to enhance the fit of the prosthesis 710 in the medullary canal 38 during implantation.

In use and as best seen in Fig. 7A, an external transducer 12 emits acoustic waves 30 towards the upper portion 720 of the wedge member 732. The acoustic waves 30, in turn, travel along the outer periphery of the wedge member 732 and are trapped within the specified pattern thus propagating the waves 30 within the pattern between the wedge member 732 and the medullary canal. It is contemplated that these patterns promote better ultrasound coverage and, thus, enhance the coverage of bony ingrowth.

Fig. 7B shows one particular embodiment of the present disclosure which includes a vertical groove pattern 755 which extends along the outer periphery of the prosthesis 710 to conduct acoustic waves 30 into the medullary canal 38. This particular embodiment also includes a series of downwardly angled bridges 765 disposed between adjacent grooves 755 which provide alternate paths for the acoustic energy 30 should a groove 755 become saturated with bony ingrowth.

For the purpose of analysis, the etched patterns/grooves 755 on the outer surface of the prosthesis 710 can be considered to be a unique collection of rectangular waveguides, each of dimensions d_x and d_y and open in the z-direction. If a particular choice of "n" and "m" specifies one of the possible normal modes of vibration, then the cutoff frequency (f_c) for the nm^{th} mode is:

$$f_c = (\frac{c_L}{2})\left[(\frac{n}{d_x})^2 + (\frac{m}{d_y})^2\right]^{\frac{1}{2}}$$

For n=m=1, the longitudinal velocity of sound c_L = 1500 meters per second, then the cutoff frequencies for the channels are:

$d_x=d_y=6mm$, $f_c \geq 177$ kHz; $d_x=d_y=3mm$, $f_c \geq 354$ kHz; $d_x=d_y=1.5mm$, $f_c \geq 707$ kHz.

Insonification of the channels 755 at frequencies much lower than f_c will produce vibrational modes of primarily shear waves.

Since the femur is generally cylindrical and about one-forth of the body weight and if the channel 755 is considered to be a about two-thirds of the femur length and if the channel 755 is filled with body fluid, blood, and some tissue debris, then the ultrasound absorption can be assumed to be about 0.3 dB per MHz per cm. For example, the femur of a person who is six feet tall is about eighteen inches in length, thus, the prosthesis 710 should have a grooved channel 755 about nine inches (23 cm) in length. If the transmitted frequency is 1.0 MHz, then the maximum absorption incurred for this channel size is about 7dB, or an 80% reduction in acoustic intensity from the proximal to distal end. The acoustic power is variable to ensure sufficient spatial average-temporal average (SATA) intensity levels along the channel 755 to induce bony tissue ingrowth through ultrasound stimulation.

If the conventional porous coatings on the prosthesis are distributed at strategic locations, primarily at the proximal end, an acoustic mode can be produced to generate shear waves at these specific locations to enhance bony tissue ingrowth - a type of induced "spot tissue-welding".

Preferably, the frequency of wave 30 and the channel/groove 755 sizes are varied to promote bony ingrowth from the distal to proximal ends of the prosthesis. It is contemplated that by promoting bony growth in this fashion, the entire prosthesis 710 can fuse within the medullary canal 38 of the bone.

Alternatively, the wedge member 732 can also include an internally disposed resonating chamber which can be configured and dimensioned similar to the resonating chamber of Fig. 1 to propagate waves internally through the wedge member 732. As such, acoustic waves can be propagated along the outer periphery of the wedge member 732 and within the resonating chamber, respectively, to enhance the bony ingrowth.

Although the channels 755 shown herein are shown to have a U-shaped cross-section, it is envisioned that other shapes can be used to which may promote enhanced fusion of the prosthesis 710 with the bony tissue ingrowth, e.g., undercut, rectangular and/or hemispherical.

Figs. 8 and 9 illustrate a reflected diagnostic system for determining, e.g., whether any one of the aforedescribed ultrasonic therapies are required, i.e., the prosthesis has loosened with the medullary canal. More particularly, Fig. 8 shows a main unit 11 equipped with a send/receive probe 15 which is placed in contact with the prosthesis 10. A signal is applied from unit 11 through cable 13 to probe 15 and to prosthesis 10. The return signal from the prosthesis is received by the receive portion of the probe after the signal propagates/travels through the prosthesis. Preferably, the main unit 11 includes a learned neural net which compares prior data and actual live data to determine prognosis, i.e., the return signal is analyzed and compared to prior acoustic/signal data taken at the time of implantation or last treatment to determine if the prosthesis 10 has loosened and/or the extent of bony ingrowth.

Fig. 9 shows an alternative diagnostic system wherein a second needle and/or sensor array 23 is placed adjacent the bottom of the prosthesis 10 to directly receive the primary signal from the main unit 11 at predetermined points along the prosthesis. The signal is then analyzed and compared to prior acoustic/signal data taken at the time of implantation or last treatment to determine if the prosthesis 10 has loosened. Preferably, the sensor array 23 will give progressive readings and relay the information back to the main unit 11 via cable 21.

Figs. 10A-10J show an alternate embodiment of the present disclosure which includes a knee joint prosthesis 810a having an upper prosthetic implant 820a and a lower prosthetic implant 830a which are designed to engage one another to form the prosthetic joint. Upper implant 820a is generally U-shaped and dimensioned to receive and encompass the patella 816 of the femur 814. Lower implant 830a is generally T-shaped and dimensioned to fit atop the distal end of the tibia 818. During knee joint replacement surgery, the surgeon removes the diseased portion of the bone, surrounding tissue and cartilage from the joint and reshapes the patella 816 and the distal end of the tibia 818 to receive upper and lower implants 820a and 830a, respectively (see Fig. 10E).

Preferably, the upper implant includes a pair of dowels 842a which project from the implant 820a and are generally dimensioned to engage a corresponding pair of bores 872 which are drilled into the patella 816. Likewise, the lower implant 830a includes a dowel 832a which engages a corresponding bore 870 which is drilled into the distal end of the tibia 818. Preferably, the dowels 842a and 832a include a plurality of channels or grooves 840a which extend along the length of the dowels 842a and 832a and which provide a dual function: 1) facilitate insertion and stability of the dowels within bores 870 and 872; and 2) provide a pathway to propagate acoustic energy 30' into the bone 816, 818 to stimulate bony ingrowth. In some cases the surgeon can use a special glue or cement to bond the implants 820a, 830a to the existing healthy bone 816, 818. In other cases the implants 820a, 820b can include a porous

biocompatible material which permits the patient's own bone to grow into the pores and hold the implants 820a, 830a in place.

Preferably, the inner periphery of both the upper and lower implants 820a, 830a also include a plurality of grooves 847a and 845a, respectively, which also stabilize the upper and lower implants 820a, 830a atop the bone 816, 818 and provide a pathway for the acoustic energy 30' to stimulate bony ingrowth.

As seen best in Fig. 10B, the top portion of the lower implant 830a includes a pair of rectilinear recesses 850a which are designed to seat the lowermost portion of the upper implant 820a in a cradle-like manner. This permits a natural, rocking motion of the implants 820a, 830a relative to one another which mimics the natural motion of the original knee joint. Once the upper and lower implants are engaged, the muscles and ligaments which surround the knee joint are replaced and cooperate to retain the joint 810a in place.

Figs. 11A and 11B show an alternate embodiment of a knee prosthesis of the present disclosure which includes similar upper and lower implants 820b and 830b which engage one another in a similar cradle-like fashion to form the prosthetic knee joint 810b. More particularly, upper and lower implants 820b, 830b are generally shaped to engage the patella 816 and distal end of the tibia 818, respectively, in a similar manner as described above with

respect to the Figs. 10A-10H embodiment with the exception that instead of grooves, each dowel 842b and 832b includes an elongated resonating chamber 843b and 833b, respectively, which extends the length thereof.

As seen best in Fig. 11B, upper and lower implants 820b and 830b also include side channels 823b and 822b, respectively, which carry the acoustic energy 30' toward the resonating chambers 843b, 833b of the dowels 842b, 832b. Preferably, each side channel 823b, 822b also includes a reflective surface 845b, 835b, respectively, which directs the acoustic energy 30' into the corresponding resonating chambers 843b, 833b. Preferably, the reflected waves 30' resound off the interior walls of the resonating chambers 843b, 833b and cause the prosthesis 810b to resonate which stimulates bony ingrowth.

By resonating the prosthesis 810a or 810b, or a portion thereof, within the patella 816 and tibia 818 at specific frequencies for short, e.g., 20 minute, periods of time on a weekly, bi-weekly, daily, or other time-specific basis, the energy will stimulate the soft cancellous bone which surrounds the dowels 842a,b and 832a,b to grow inwardly and stabilize the upper and lower members 820a,b and 830a,b .

Figs. 12A-12C show yet another embodiment of the present disclosure which includes an elbow prosthetic implant 910a designed to engage the lower end of the humerus 914 and upper end of the ulna 916. More

particularly, the prosthetic device 910a includes a pair of tapered, spike-like insertion members 920a and 930a which are pivotally joined to one another about a pivot 935a. Upper spike member 920a is dimensioned to insert into bore 922 which is drilled into the medullary canal 928 of the ulna 916 preferably between the olecranon process and the coronoid process. Lower spike member 930a is dimensioned to insert into bore 932 which is drilled through the olecranon depression 21 and into the medullary canal 938 of the humerus. In much the same manner as described with the above prosthetic devices, the surgeon can use special glues or cement to bond the spike members 920a, 930a to the existing healthy bone 916, 918 or porous materials which permit the patient's own bone to grow into the pores and hold the spike members 920a, 930a in place.

Preferably the outer periphery of each of the spike members 920a, 930a includes a plurality of grooves or channels 942a and 940a, respectively, which facilitate insertion and stabilization of spike members 920a and 930a within bores 928, 938 and also provide pathways for the propagation of acoustic energy 30' into bones 816, 818 to stimulate bony ingrowth. In use and as seen best in Fig. 12C, an external transducer 12 emits acoustic waves 30 towards the lower spike member 930a. The acoustic energy 30', in turn, travels along the outer periphery of the spike member 930a between the spike member 930a and the medullary canal 938 to stimulate bony ingrowth.

As mentioned above, the spike members 920a, 930a are joined to one another by pivot 935a which permits natural, pivotal motion of the spike members 920a, 930a relative to one another to mimic the natural motion of the original elbow joint.

Figs. 13A-13C show an alternate embodiment of an elbow prosthesis 910b according to the present disclosure which includes similar upper and lower spike members 920b and 930b which are joined about pivot 935b to form the prosthesis 910b. Much like the embodiment shown in Figs. 12A-12C, spike members 920b and 930b are shaped for insertion into corresponding bores 922, 932, respectively, drilled into the medullary canals 928, 938 of the ulna 916 and the humerus 914. However, instead of grooves disposed along the outer periphery of the spike members 920b, 930b, each spike member 920b, 930b includes an elongated resonating chamber 924b and 934b, respectively, which extend the length thereof towards respective distal ends 926b and 936b.

As seen best in Fig. 13C, external ultrasonic transducer 12 emits acoustic waves 30 which are transcutaneously delivered through the body tissue towards the prosthesis 910b. Preferably, the acoustic wave 30 is focused at openings 923b, 933b such that a majority of the wave energy enters openings 923b, 933b of resonating chambers 924b, 934b and resounds off the interior walls of resonating chamber 9244b, 934b and causes each spike member 920b, 930b to resonate. In some cases it may be preferable to fill resonating chamber 924b,

934b with a fluid to facilitate propagation of the acoustic wave 30' through the resonating chambers 924b, 934b.

By resonating the spike members 920b, 930b within the medullary canals 928, 938, the resounding energy will stimulate the soft cancellous bone which surrounds the canals 928, 938 to grow inwardly and stabilize the prosthesis 910b within the bones 916, 914.

From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the present disclosure. For example, in some case it may be preferable to employ a converter to convert ultrasound to the power transducer and/or use an audio signal to activate an internally housed transducer. Although it is preferable to fill the resonating chamber with a ultrasound conducting fluid, in some cases it may be preferable to shape the resonating chamber as a resonating horn filled with a solid material.

Although the various prosthetic devices of Figs. 10-13 show resonating chambers similar in construction to the resonating chamber of Fig. 3, it is contemplated that various resonating chambers described herein may be used in combination with the prosthetic devices of the Figs. 10-13 embodiments. Likewise, it is contemplated that the various patterns shown on the outer

periphery of the prostheses shown with respect to Figs. 7A-7E can be employed on the prosthetic devices shown in Figs. 10-13.

In addition to the internal and external waveguides shown herein, it is envisioned that the structure can be used in conjunction with porous coatings of the type known in the art either arranged in predetermined patterns or uniformly, see, e.g., U.S. Patent No. 4,536,854, U.S. Patent No. 5,018,285 and U.S. Patent No. 5,004,476.

The various embodiments of the present disclosure provide configurations which cooperate with ultrasonic therapies to induce bony ingrowth into the prosthetic device and provide a more stable fixation between the prosthesis and the bone. While particular embodiments of the disclosure have been described, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

CLAIMS

1. A bone prosthesis (10) comprising a first portion (32) for engaging a first bone segment (14) characterised in that the bone prosthesis (10) further comprises at least one means for propagating acoustic energy (30) to said first bone segment (14).

2. A bone prosthesis (10) according to claim 1 further comprising a second portion for engaging a second bone segment (26).

3. A bone prosthesis (10) according to claim 2 in which comprises at least one means for propagating acoustic energy to said second bone segment.

4. A bone prosthesis (10) as claimed in either of claims 1, 2 or 3 in which the at least one means for propagating acoustic energy to the corresponding bone segment comprises at least one channel.

5. A bone prosthesis (10) according to claim 4 wherein said channel includes an interior reflective surface (42) which defies a resonating chamber (34) disposed through at least one of said portions (14, 18).

6. A bone prosthesis (10) according to claim 5 wherein said resonating chamber (34) includes at least one opening (22) for receiving acoustic energy.

7. A bone prosthesis (10) according to claim 6, wherein said resonating chamber (34) is convoluted.

8. A bone prosthesis (10) according to any one of claims 4 to 7 wherein said bone prosthesis (10) further comprises a transducer (144) disposed to receive acoustic energy (30) and emit acoustic waves (30') through said channel.

9. A bone prosthesis (10) according to claim 2 wherein said means for propagating comprises a transducer collar (546) which engages one of said portions.

10. A bone prosthesis (10) according to claim 2 wherein said means for propagating includes a transducer (144) disposed adjacent at least one of said portions.

11. A bone prosthesis (10) according to claim 2 wherein at least one of said portions includes a porous coating wrapped therearound.

12. A bone prosthesis (10) according to claim 11 wherein said means for propagating includes a piezoelectric membrane material which is disposed between said porous material and an outer periphery of said portion.

13. A bone prosthesis (10) according to claim 11 wherein said means for propagating includes a piezoceramic membrane material which is disposed between said porous material and an outer periphery of said portion.

14. A bone prosthesis (10) according to claim 4 wherein the prosthesis includes a ball portion for engaging the acetabulum (16) of the pelvic bone (26) and said first portion is an implant for engaging the medullary canal (38) of the femur (14).

15. A bone prosthesis (10) according to claim 14 wherein said channel includes an interior reflective surface (42) which defines a resonating chamber (34) disposed through said implant.

16. A bone prosthesis (10) according to claim 15 wherein said resonating chamber (34) includes at least one opening (22) for receiving acoustic energy (30).

17. A bone prosthesis (10) according to claim 14 wherein an outer periphery of said implant (732) is patterned to promote acoustic wave propagation along an outer surface of said implant.

18. A bone prosthesis (10) according to claim 15 wherein said resonating chamber (34) includes a plurality of slots which

extend outwardly from said resonating chamber (34) to transmit acoustic energy (30) directly to the medullary canal (38).

19. A bone prosthesis (10) according to claim 4 wherein the first portion engages the medullary canal (38) of the humerus and a second portion engages the medullary canal of the ulna; and wherein said first and second portions are movable relative to one another about a pivot.

20. A bone prosthesis (10) according to claim 19 wherein each of said portions includes a channel, each of said channels including an interior reflective surface (42) which defines a resonating chamber (34) disposed through each of said portions.

21. A bone prosthesis (10) according to claim 20 wherein each of said resonating chambers (34) includes at least one opening (22) for receiving acoustic energy (30).

22. A bone prosthesis (10) according to claim 19 wherein an outer periphery (732) of at least one of said portions is patterned to promote acoustic wave propagation along an outer surface of said portion.

23. A bone prosthesis (10) according to claim 4 wherein the first portion engages the femur (14) and a second portion engages the tibia, said first and second portions being movable relative to one another upon movement of one of the femur and the tibia (818).

24. A bone prosthesis (10) according to claim 23 wherein said first portion includes at least one dowel (842a, 832a) which engages a corresponding bore associated with the femur (14) and said second portion includes at least one dowel (842a, 832a) which engages a corresponding bore with the tibia (818).

25. A bone prosthesis (10) according to claim 24 wherein said channel includes an interior reflective surface (42) which

defines a resonating chamber (34) disposed through each of said dowels (842a, 832a).

26. A bone prosthesis (10) according to claim 25 wherein each of said resonating chambers (34) includes at least one aperture (22) for receiving acoustic energy (30).

27. A bone prosthesis (10) according to claim 23 wherein said first and second portions include outer surfaces which pivotally engage one another and bone-facing inner surfaces which engages the femur (14) and tibia (818) respectively.

28. A bone prosthesis (10) according to claim 27 wherein said first portion is generally U-shaped and encompasses the patella of the femur (14) and said second portion is generally T-shaped and fits atop the tibia (818).

29. A bone prosthesis (10) according to claim 27 wherein said channel includes a plurality of grooves located along said bone-facing inner surface of one of said first and second portions.

30. A bone prosthesis (10) according to claim 24 wherein at least one of said dowels of said first and second portions includes a plurality of grooves for propagating acoustic energy (30) therethrough.

31. A bone prosthesis (10) according to claim 27 wherein said outer surface of said second portion includes at least one recess for seating the outer surface of said first portion in a cradle-like manner.

32. A method for measuring the stability of an implanted prosthesis (10) comprising the steps of:

a) providing a source having a probe for sending and receiving signals and a comparator for comparing and analysing prior signal data with newer signal data;

b) placing said probe adjacent said prosthesis (10);

c) transmitting an initial signal through said probe to said prosthesis (10);

d) receiving a return signal from said probe after said signal propagates and returns through said prosthesis (10);

e) storing said return signal data;

f) repeating steps (a) through (e); and

g) comparing and analysing stored return signal data to determine implant stabilization.

33. A method for measuring the stability of an implanted prosthesis (10) comprising the steps of;

a) providing a source having a probe for sending signals and a comparator for comparing and analysing prior signal data with newer signal data;

b) providing a receiving sensor which connects to said source and monitors said signals as said signals propagate through said prosthesis (10);

c) placing said probe adjacent said prosthesis (10);

d) placing said receiving sensor along said prosthesis (10);

e) transmitting signals through said probe to said prosthesis (10);

f) monitoring said signal with said receiving sensor as said signal propagates through said prosthesis (10);

g) storing said signal data;

h) repeating steps (a) through (g); and

i) comparing and analysing stored signal data to determine implant stabilization.

34. A method for stabilizing an implanted prosthesis (10) comprising the steps of:

a) providing a bone prosthesis (10) having a first portion and at least one channel for propagating acoustic energy (30) therethrough;

b) engaging said first portion within a first a bone segment; and

c) periodically directing acoustic energy (30) at said first portion such that acoustic energy (30) is transmitted through said channel to said first bone segment to stimulate bony ingrowth.

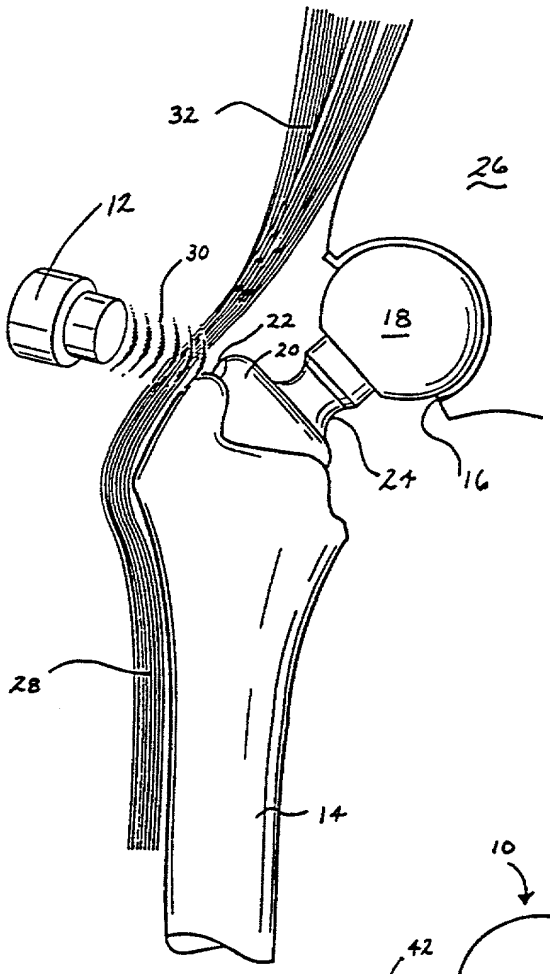


Fig. 1A

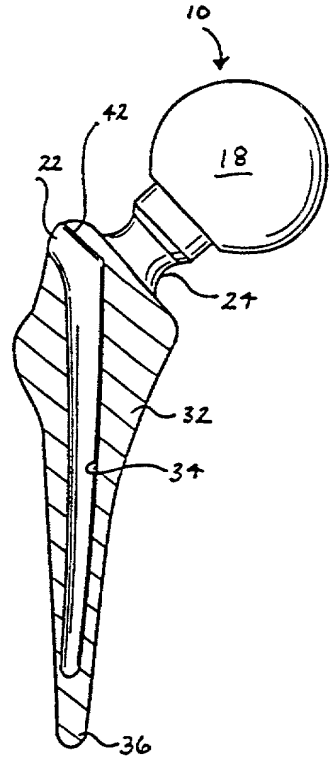


Fig. 1B

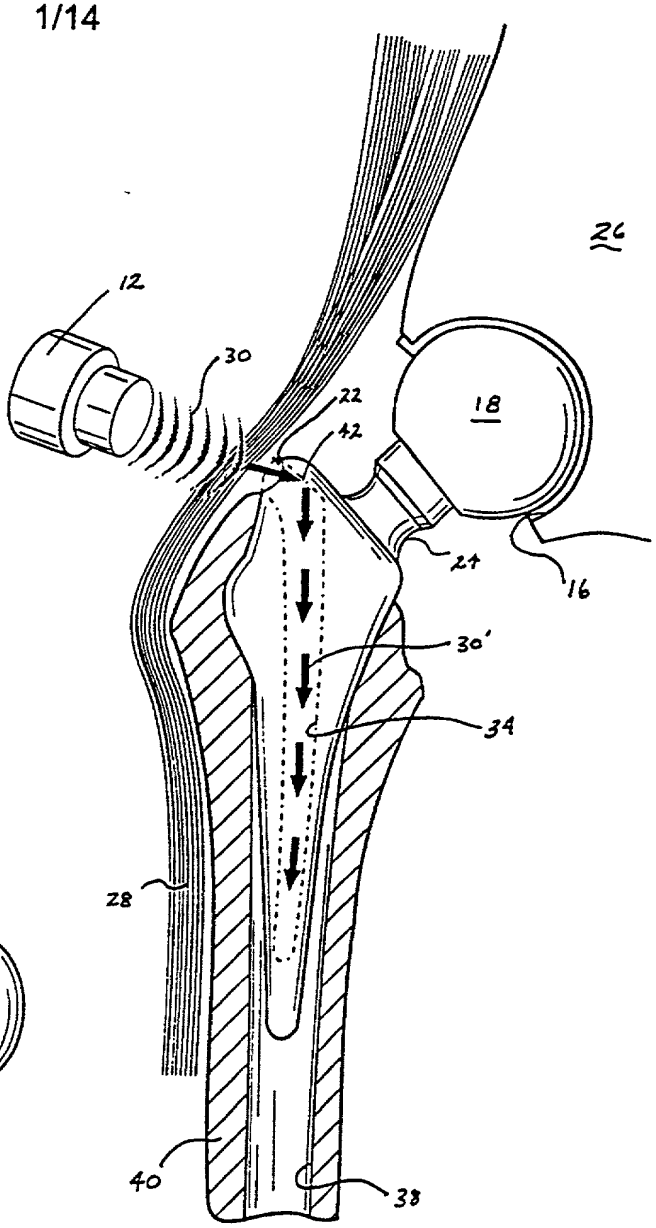


Fig. 1C

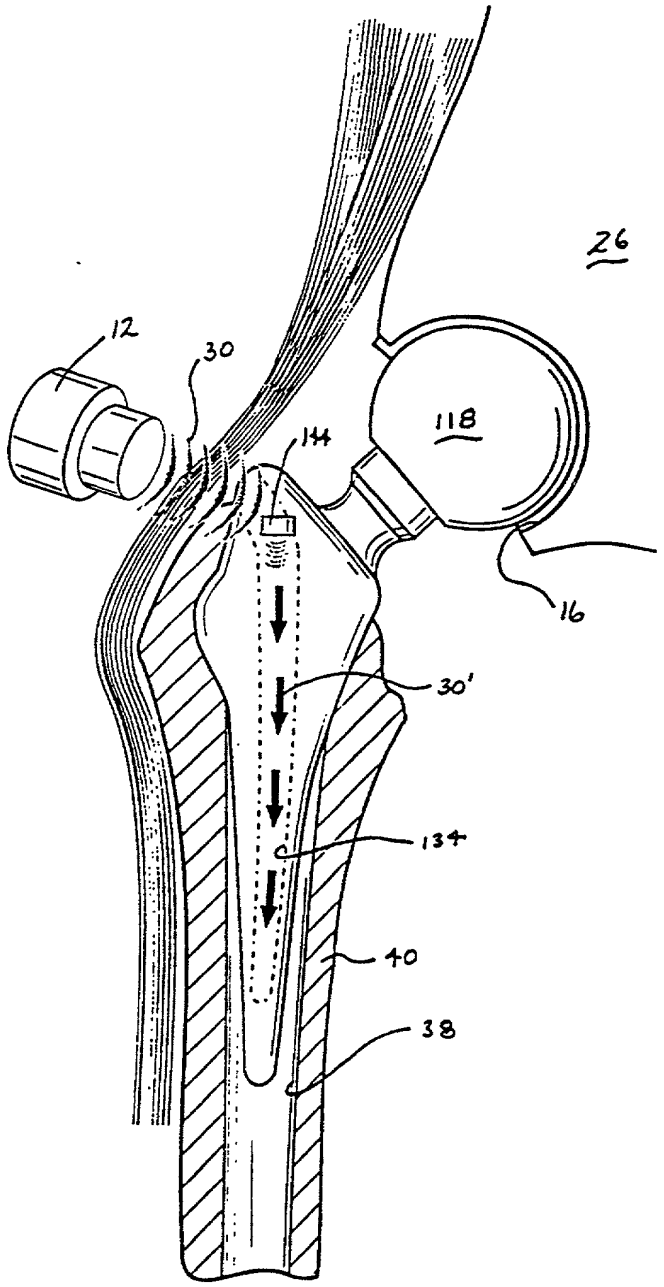


Fig. 2B

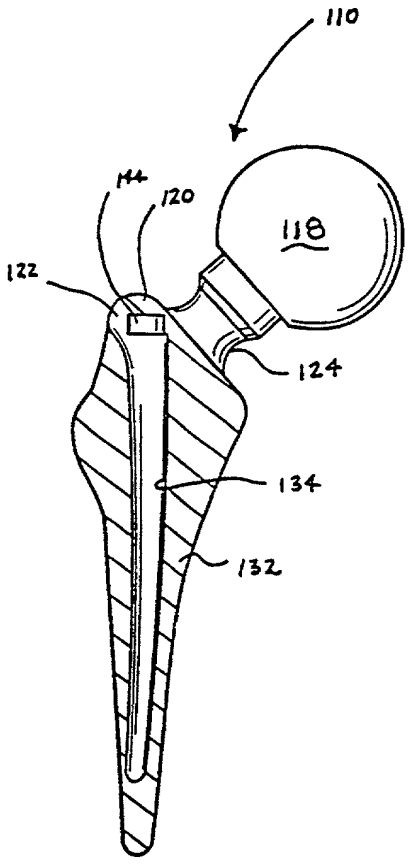


Fig. 2A

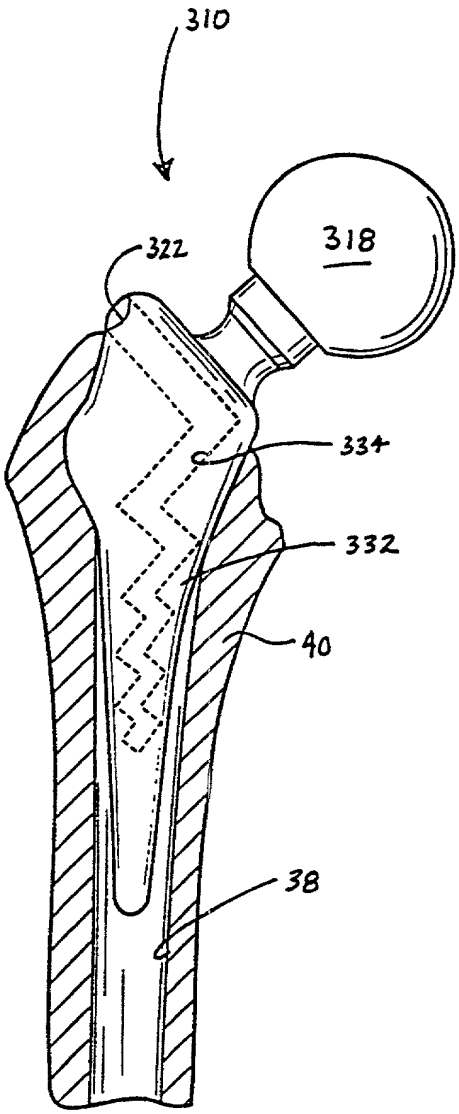


Fig. 3

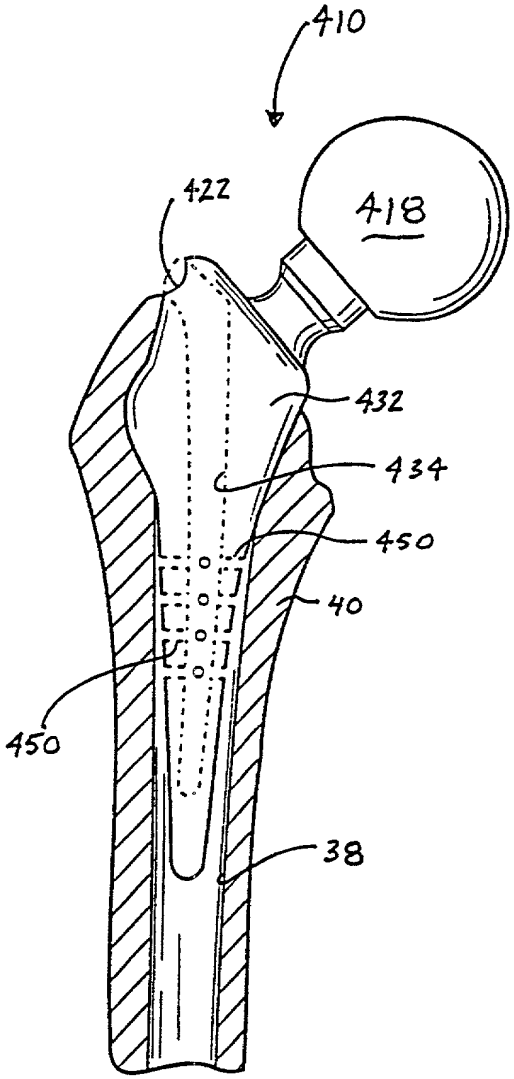


Fig. 4

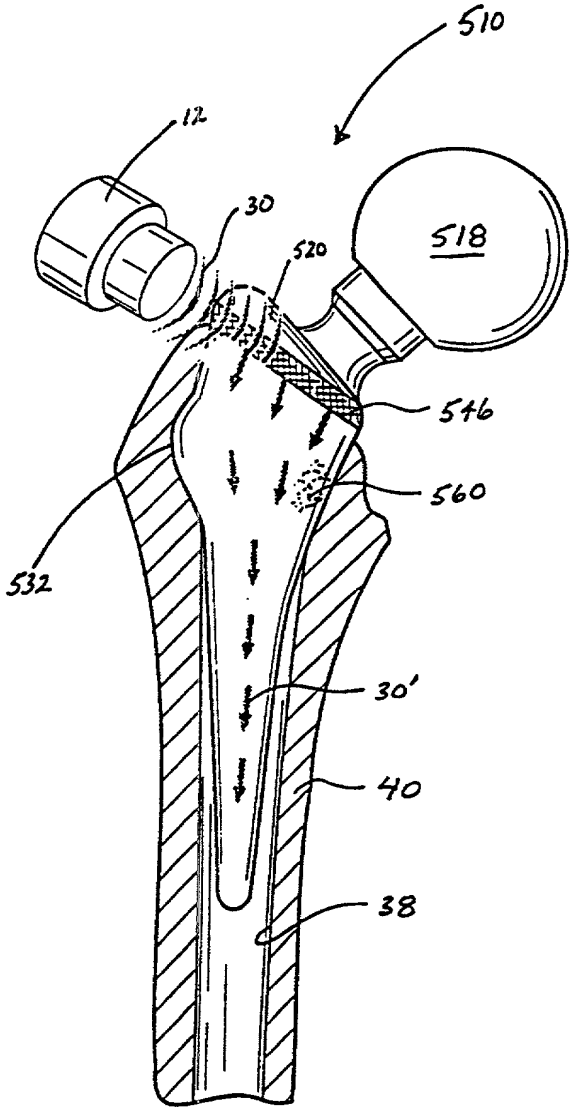


Fig. 5A

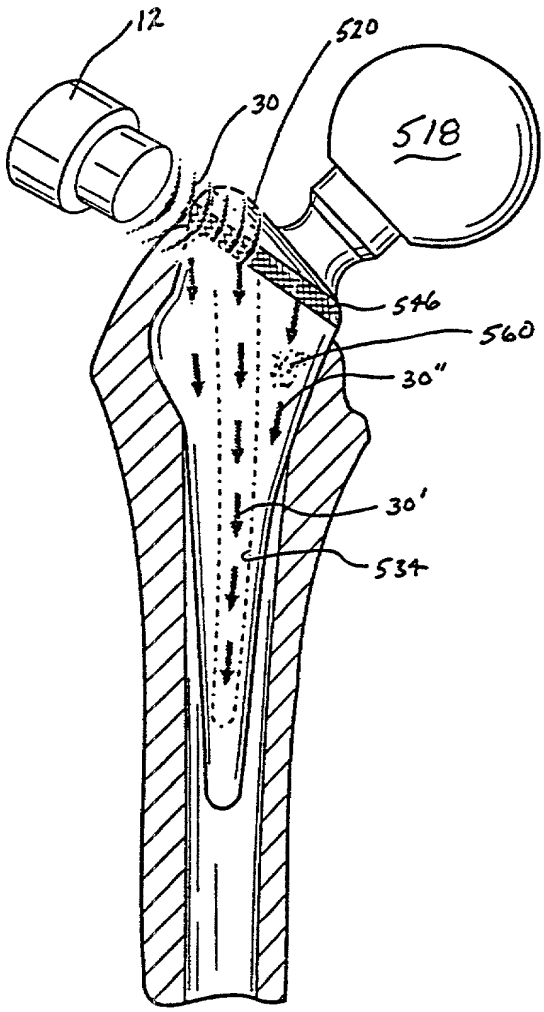


Fig. 5B

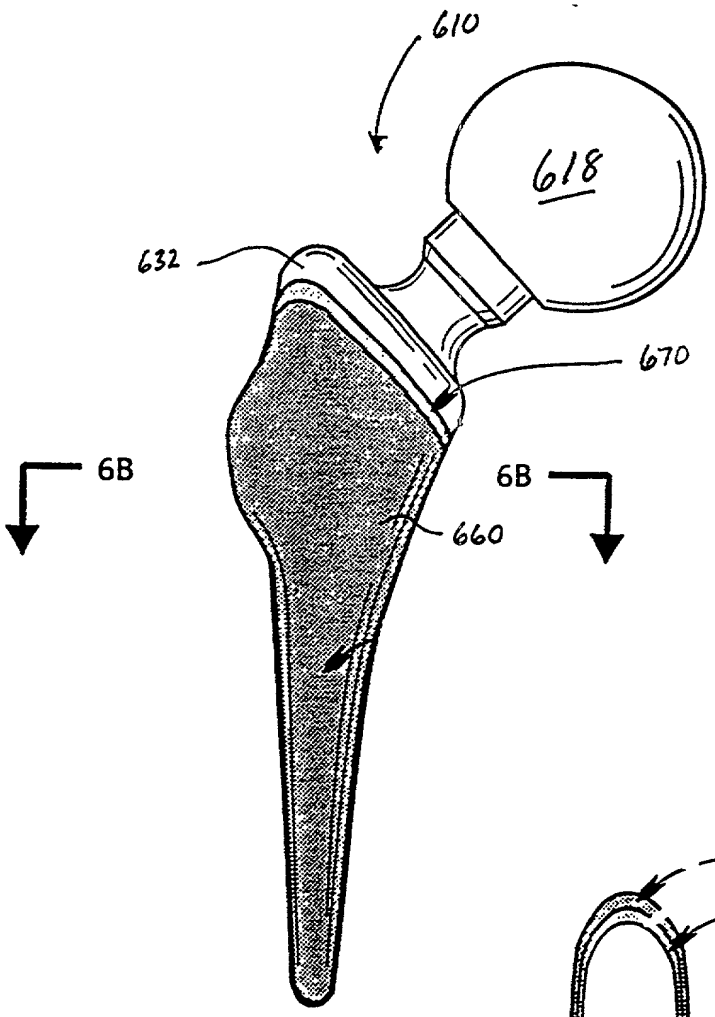


Fig. 6A

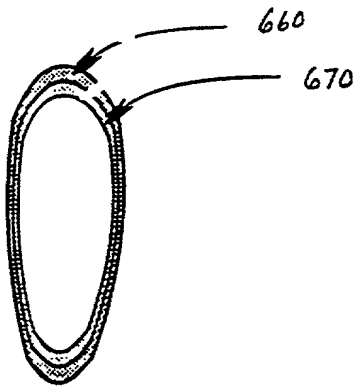


Fig. 6B

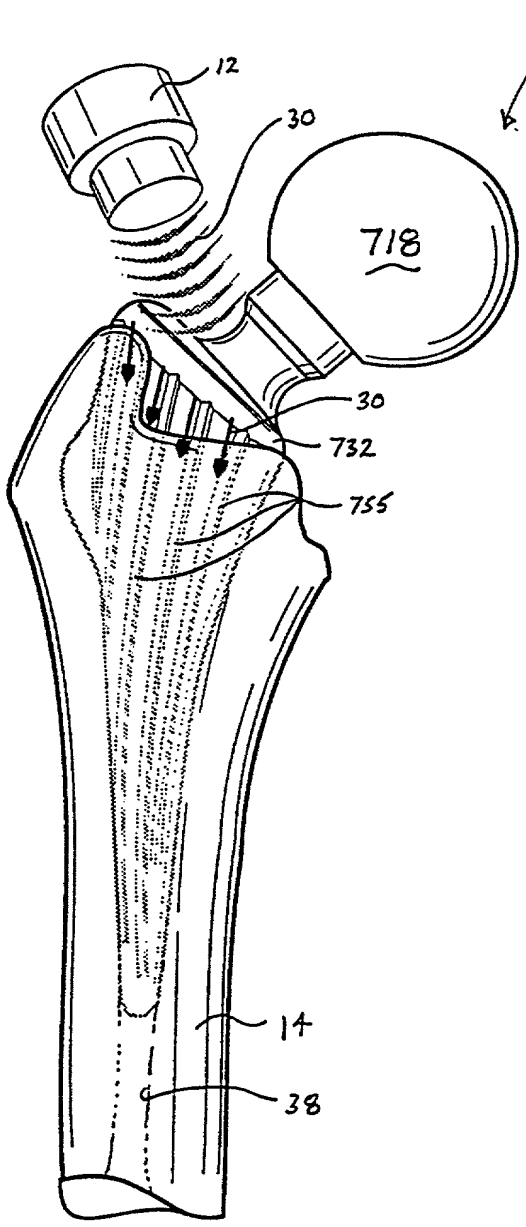


Fig. 7A

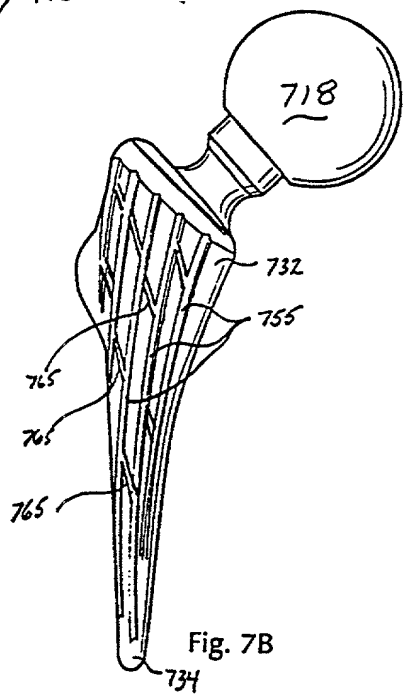


Fig. 7B

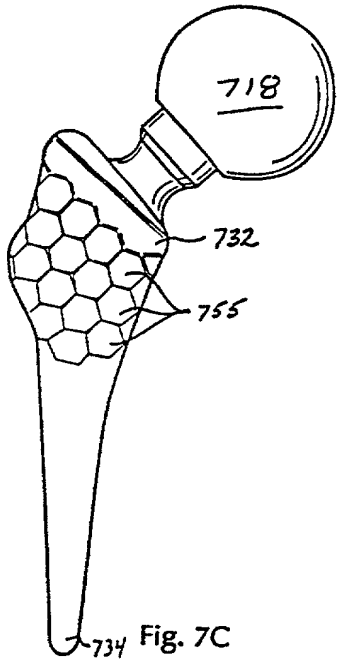


Fig. 7C

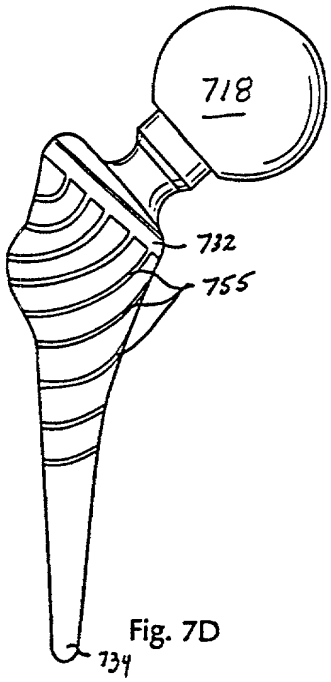


Fig. 7D

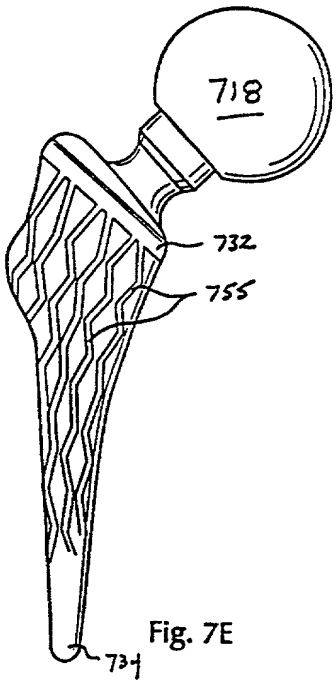


Fig. 7E

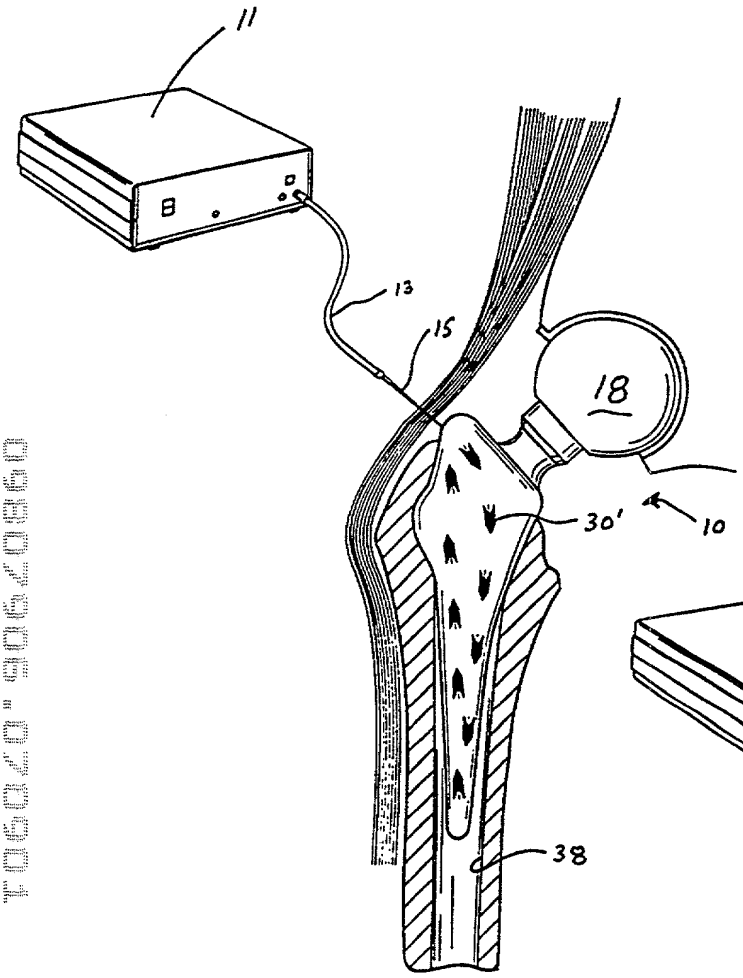


Fig. 8

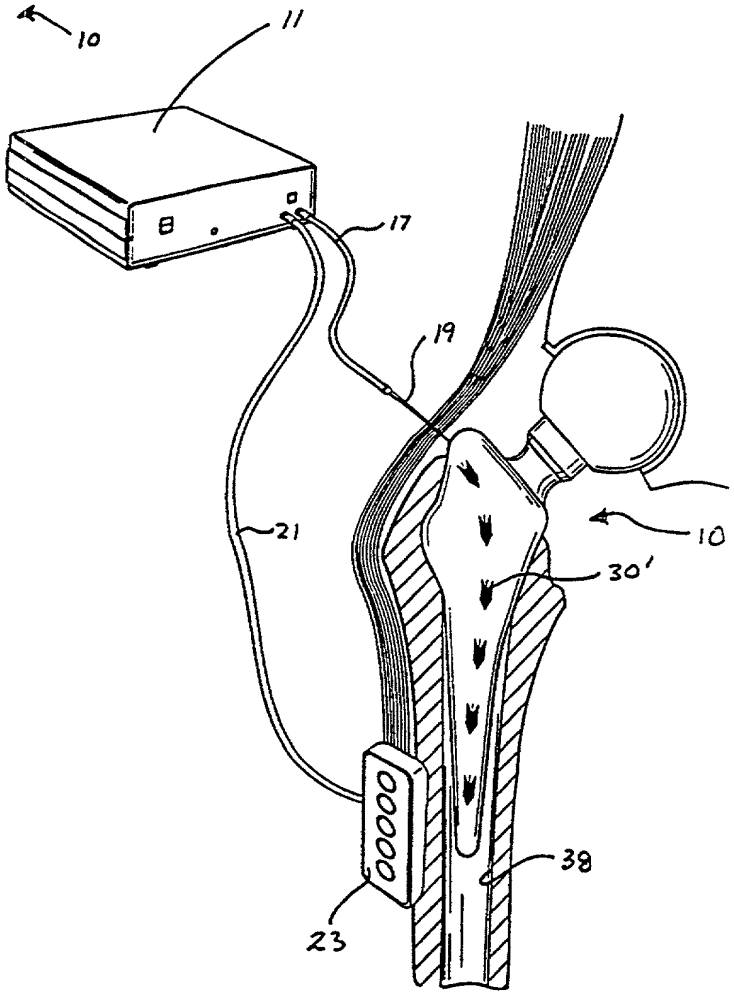


Fig. 9

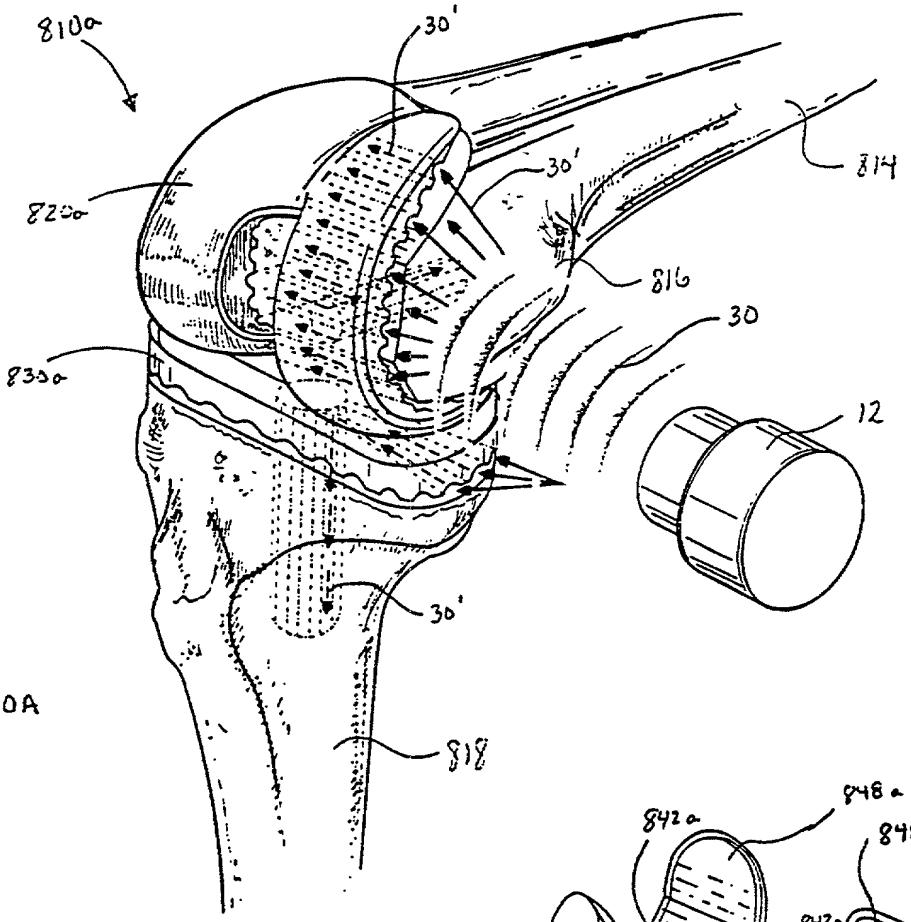


FIG. 10A

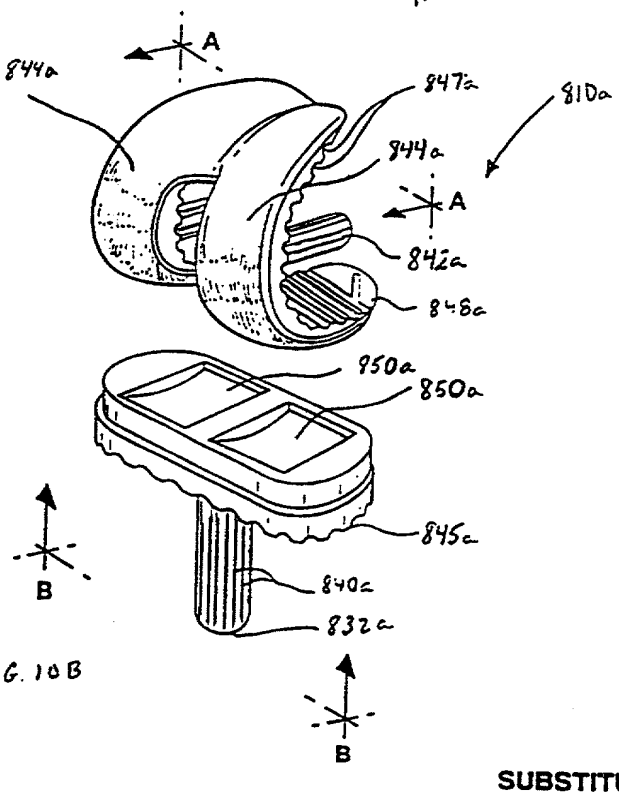


FIG. 10B

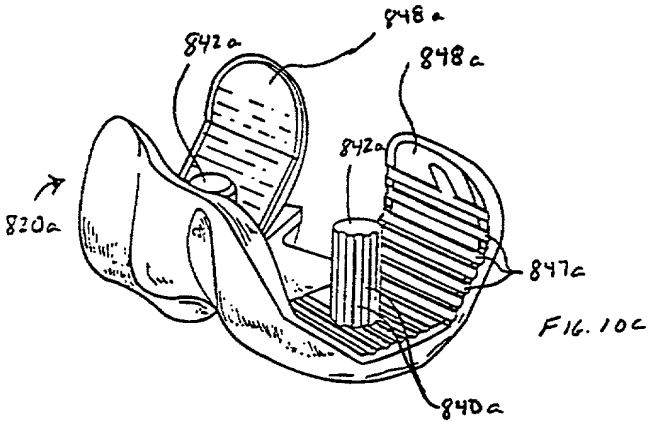


FIG. 10C

FIG. 10I

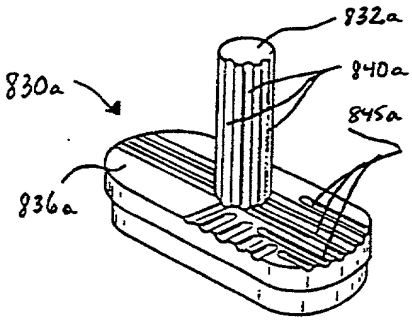


FIG. 10D

FIG. 10J

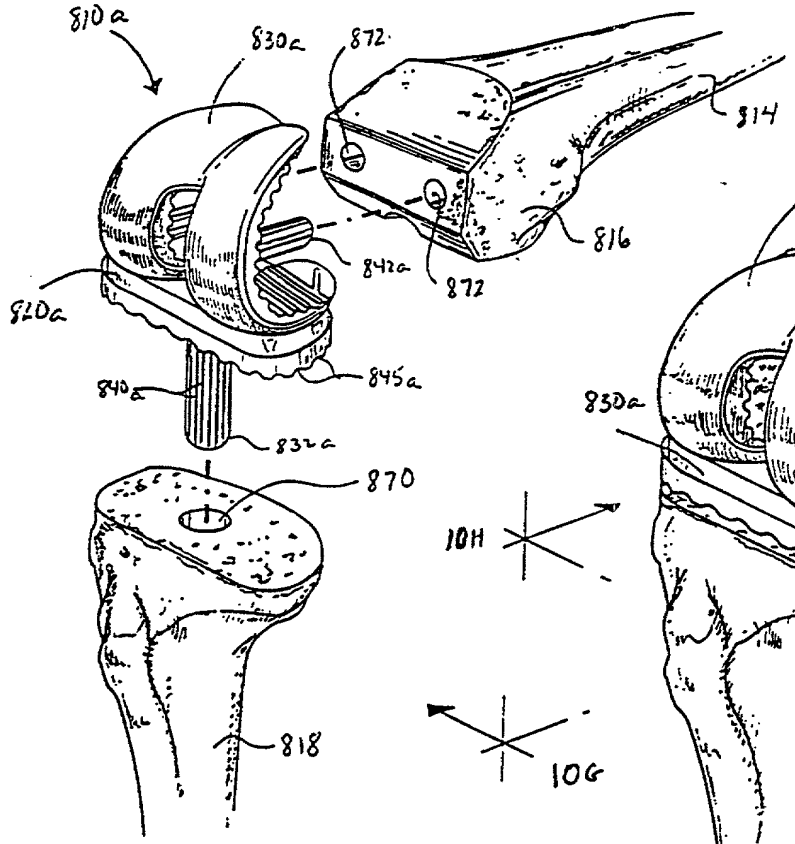


FIG 10E

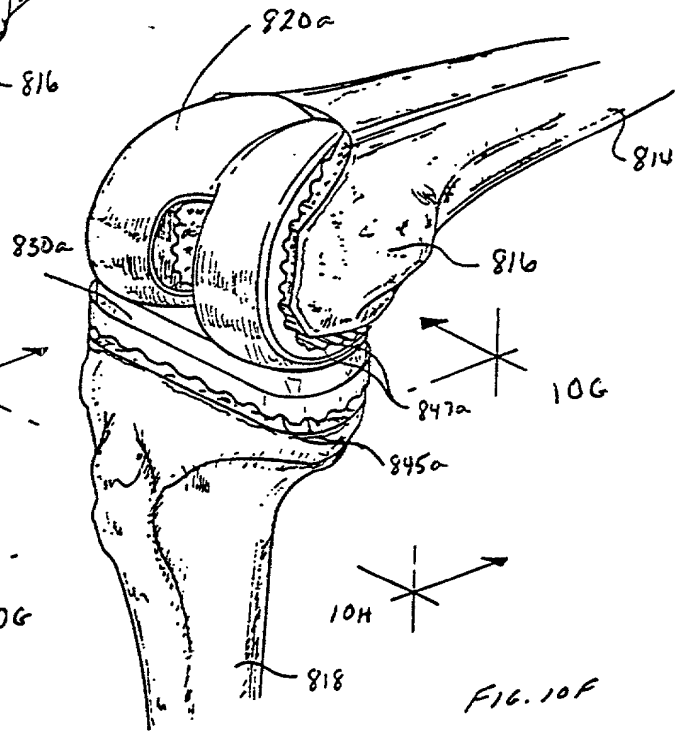


FIG. 10F

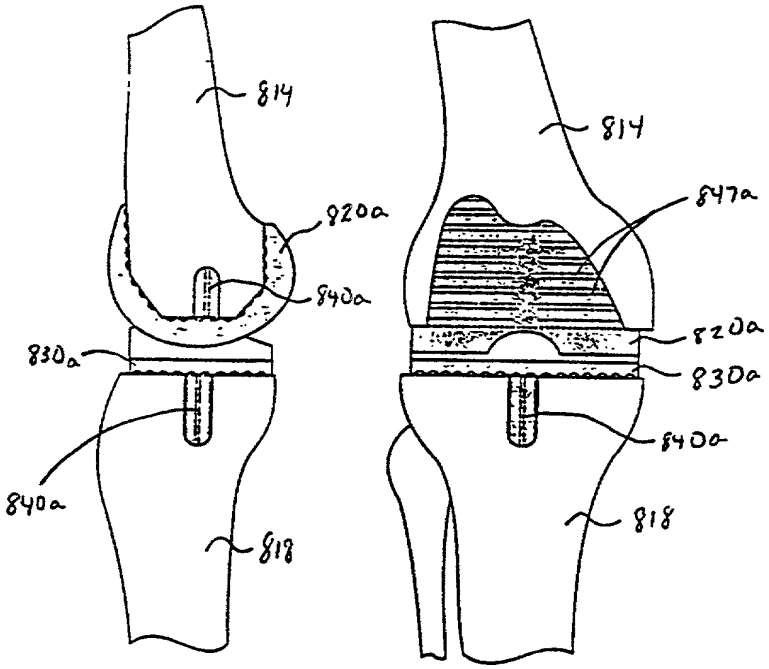


FIG. 10G FIG. 10H

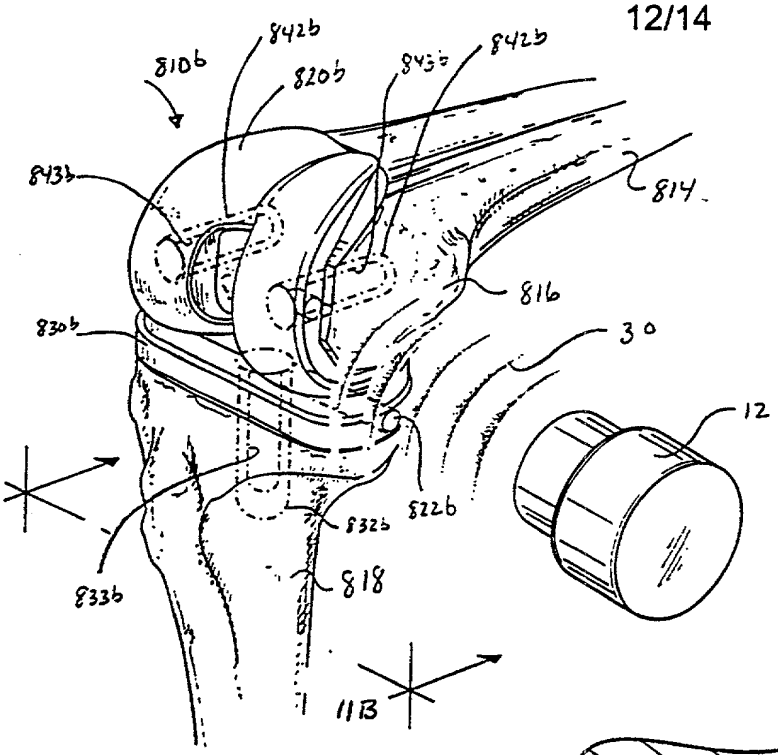


FIG. 11A

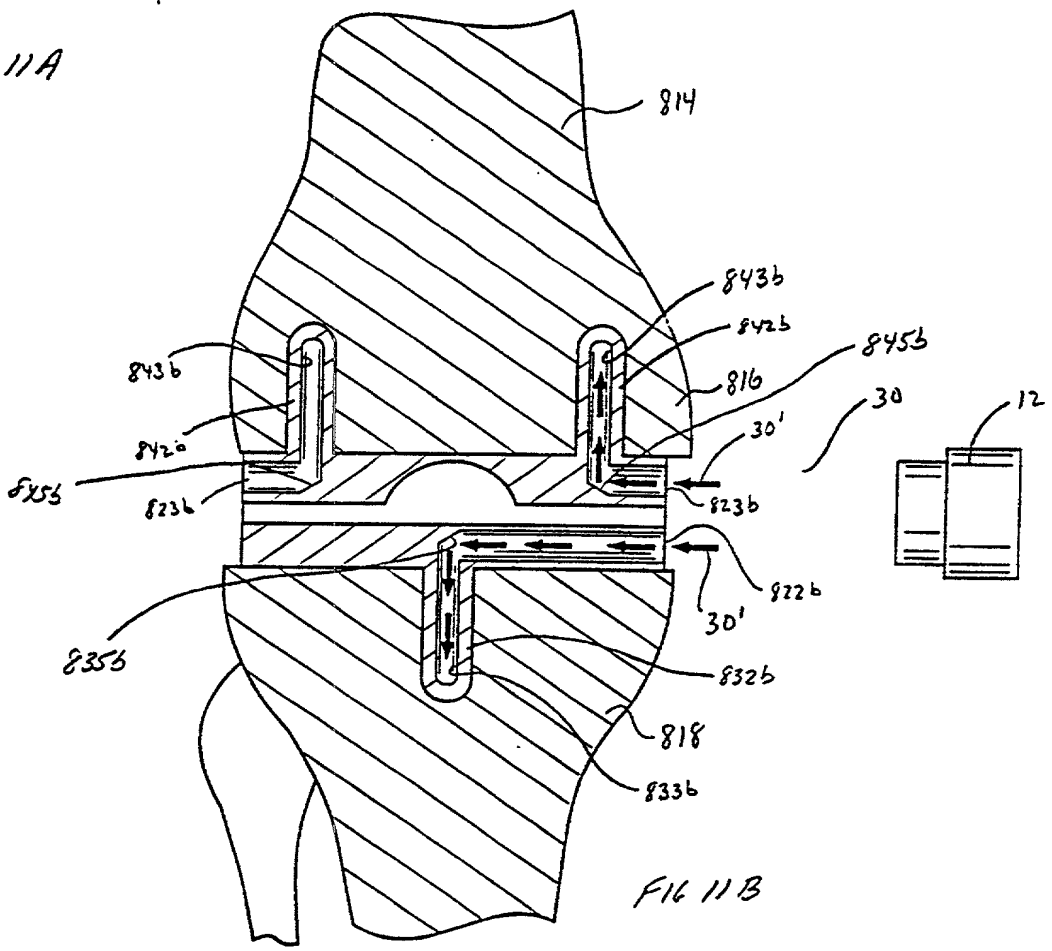


FIG 11B

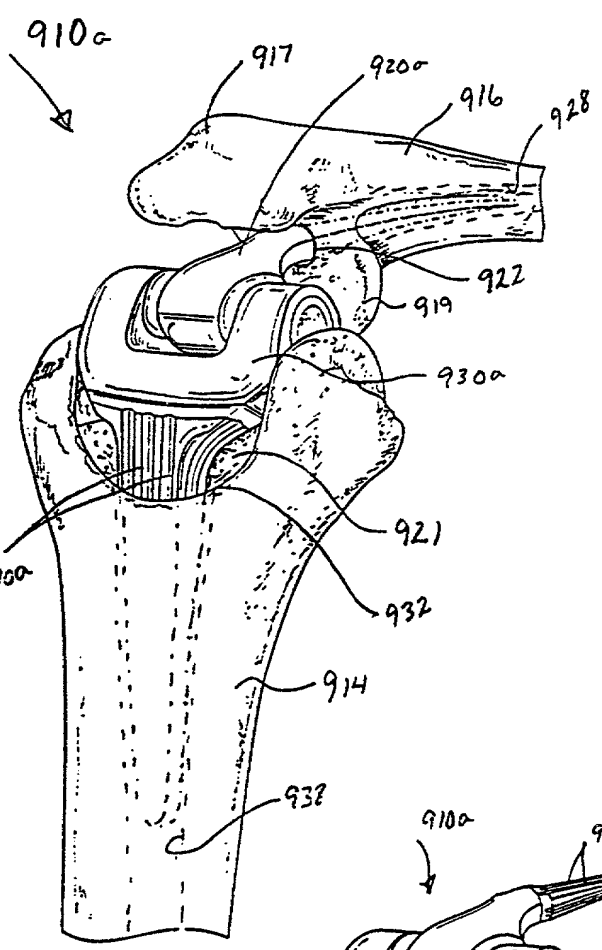


FIG. 12A

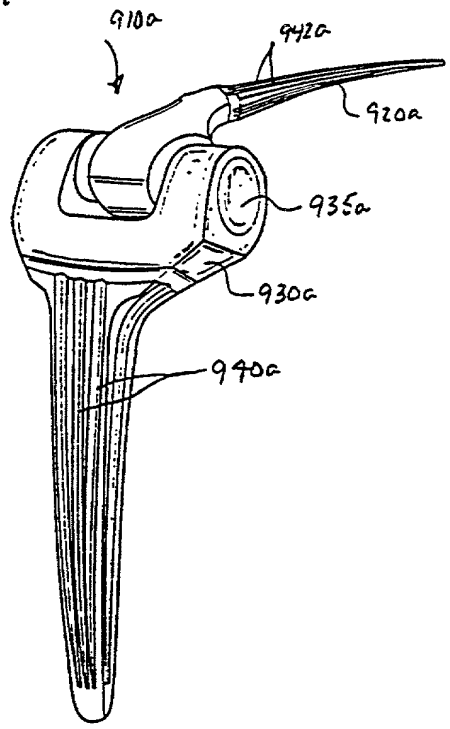


FIG. 12B

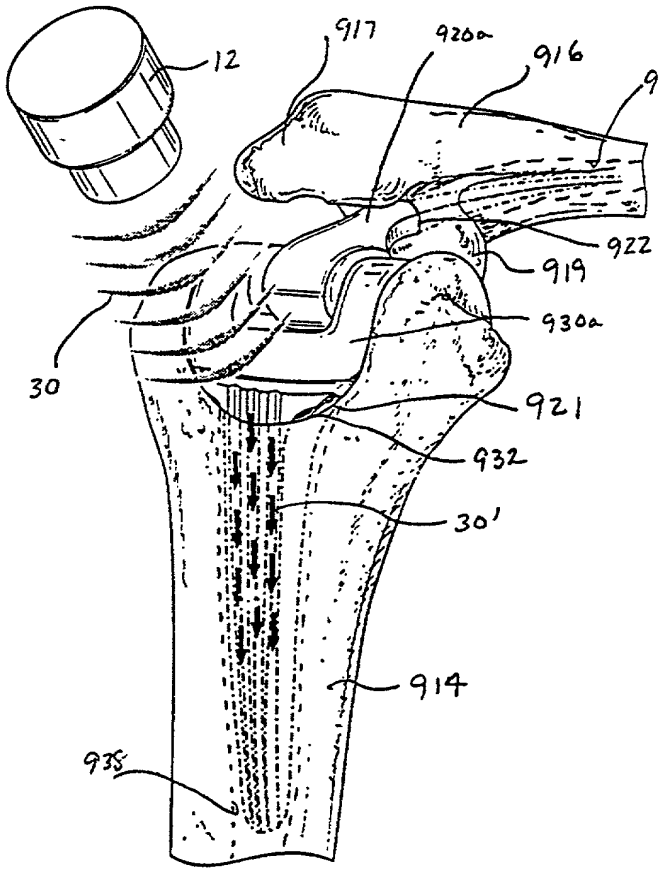
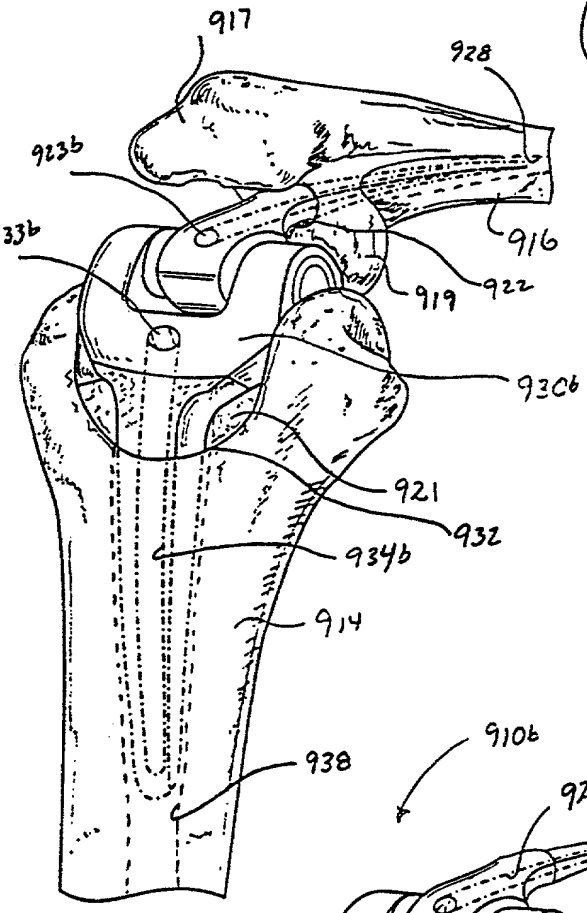
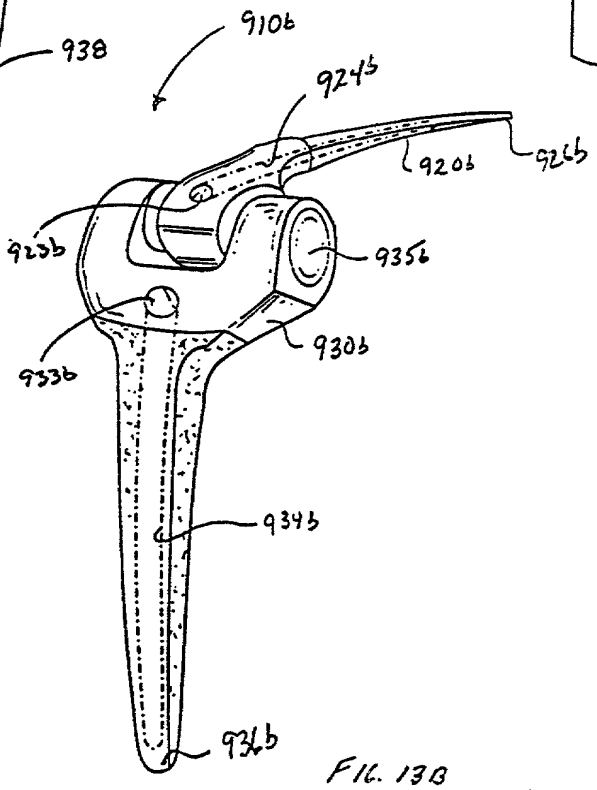


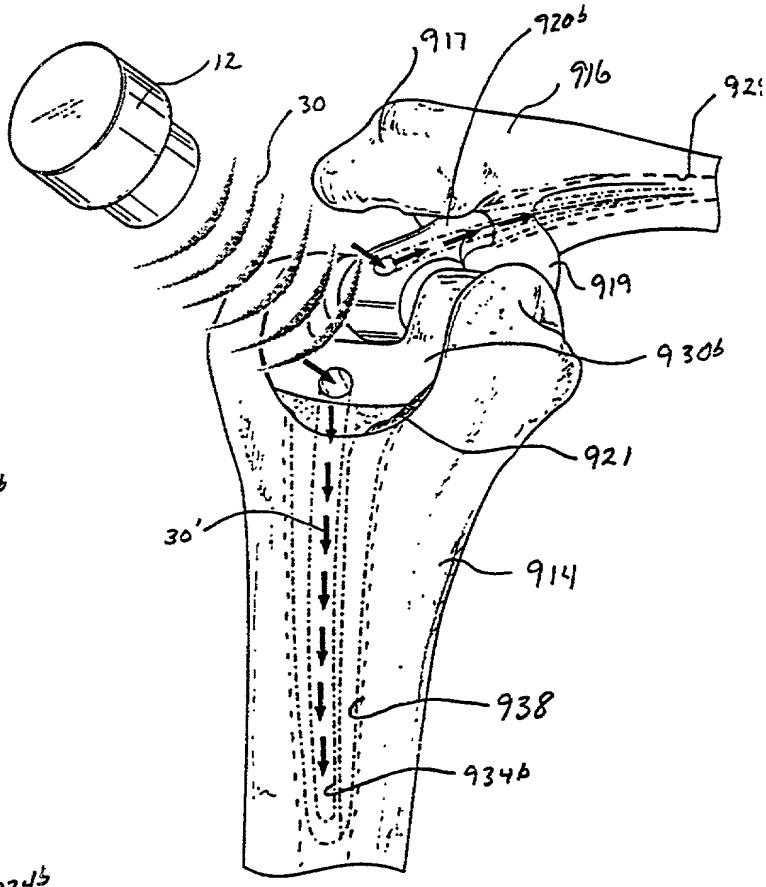
FIG. 12C



F16 13A



F16. 13B



F16. 13C

#3

Attorney Docket No. 41482/205539
Express Mail Label No. EL572470413US

DECLARATION FOR PATENT APPLICATION

☒ Original ☐ Supplemental ☐ Substitute ☐ PCT

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below), or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Prosthesis and Methods of Inducing Bony Ingrowth Using Ultrasound Therapy
(Title of the Invention)

the specification of which (check one)

☐ is attached hereto

☒ was filed on 12 November 1999 as PCT/US99/26265

and was amended on 15 January 2001 (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 (a) - (d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified, by checking the box below , any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Applications			Priority Claimed		Copy Attached	
Application Number	Country	Foreign Filing Date (MM/DD/YYYY)	YES	NO	YES	NO

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below and claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application(s) designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Parent Application Number	Filing Date	Status (Mark Appropriate Column Below)		
		Patented	Pending	Abandoned
60/108,235	11/13/98 (November 13, 1998)			x

As a named inventor, I hereby revoke all prior powers and appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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